REMARKS

This is responsive to the Office Action mailed on January 5, 2010. Claims 1 and 13-32 are pending in the application. Claims 17-22, 28 and 30 have been withdrawn. Claims 1, 13-16, 23-27, 29 and 31-32 stand rejected. Applicants have amended claims 1, 14, and 15 have been amended. No new matter was added.

Rejections over 35 U.S.C. 112, second paragraph

The Office Action rejected claims 1, 13-15, 27, 29 and 31-32 under 35 U.S.C. 112, second paragraphs being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action alleged that claims 1 and 13-15 and thereby dependent claims 31-32 do not provide a positive definition of the subject matter for which patent protection is sought because the claims merely indicate what the composition must not contain and this fact leaves the claims open to countless possible food compositions. The Office Action indicated that the metes and bounds of these claims are unclear.

The Office Action also asserted that claims 13-15 list the negative limitations of amounts of polyamines by using the phrases "less than about X picomoles/g" and that the metes and bounds of these claims are unclear. The Office Action indicated that "less than" requires the amount to be less than X but the word "about" includes values larger than X and thus the two phrases contradict each other.

The Office Action also indicated that claims 27 and 29 recite the limitation "sufficient quantities of vitamins, minerals and electrolytes to satisfy the daily nutritional needs of a human being" and that it is unclear what quantities are required by the claims. The Office Action also asserted that claims 14 and 15 contain broad limitations followed by more narrow limitations due to the word "preferably" and that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection sought.

Applicants assert that amended claims 1 and 13-15 and therefore dependent claims 27, 29 and 31-32 are not indefinite. Applicants have amended claim 1 to recite that the treatment comprises a food composition for human consumption and that the food composition comprises a daily food ration. Support for this amendment can be found in the Specification on page 12, lines 21-23 and page 13, lines 10-13. The daily food ration, as is known to one of ordinary skill

in the art, can include appropriate nutrients to sustain a human being. The daily food ration can include, for example, glucides, lipids, proteins, and sufficient quantities of vitamins, minerals and electrolytes. See page 12, line 24 to page 13, line 3. One of ordinary skill in the art would understand that a wide variety of daily food rations with variable amounts of nutrients are plausible. Attached as Exhibit 1 is a daily food ration guidelines according to the American Red Cross. These daily food rations may vary depending on the persons food preference, vegetarian versus non-vegetarian, cultures, etc. The present invention encompasses all of these daily food rations with the limitation that the daily food ration contain less than the 1600 picomoles of polyamines and that this reduction in polyamines in the daily food ration affects the activity of the NR2-B subunit of the NMDA receptor. Support for this amendment is found in the Specification on page 5, lines 13-17. Applicants submit that these amendments to claim 1 provide a positive definition of the food composition and indicate that metes and bounds of the claimed subject matter.

With regard to claims 13-15, Applicants assert that the term "about" merely extends some flexibility to the number, for example, 400 picomoles. Applicants assert that the term "less than about" is not contradictory. For example, the use of 401 picomoles literally is not less than 400, however functionally a person of ordinary skill in the art would equate this as about 400. Applicants assert that this allows for flexibility such that an infringer may not use 401 picomoles to avoid infringement of the claims.

According to the MPEP, "The term 'about' used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible." See MPEP 2173.05(b)(A). Applicants assert that "less than about" used in the present claims is clear but flexible. With regard to how far reaching the term "about" truly is, according to the MPEP, "...a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention." Applicants assert that a person of ordinary skill the art would be reasonably apprised of the scope of the invention in the instant claims.

With respect to claims 27 and 29, "sufficient quantities of vitamins, minerals and electrolytes..." are amounts that can satisfy the requirements for human consumption. Applicants assert that the metes and bounds of these claims are clear to a person of ordinary skill in the art.

With respect to claims 14 and 15, Applicants have amended these claims to recite one range and not a narrow and broad range.

Based on the claim amendments and the discussion above, Applicants respectfully request the removal of the rejection based on 35 U.S.C. 112, second paragraph.

Rejections over 35 U.S.C. 112, first paragraph

The Office Action rejected claims 1 and 13-15 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Office Action asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. The Office Action alleged that claims 1 and 13-15 do not provide a positive definition of the subject matter for which patent protection is sought and that these claims merely indicate what the composition must not contain. The Office Action asserted that the claims are open to countless possible food compositions to be administered and that the Applicant has not described these compositions by structure or function to suggest that they were in possession of the full scope encompassed by the claims. The Office Action indicated that in its most generic sense page 12 of the instant specification described the composition which is described in claim 16. The Office Action cited caselaw regarding the requirement of the written description requirement. The Office Action concluded that the Applicants describe no other composition for human consumption that might be useful and have not described the genus in a manner that would allow one skilled in the art to immediately envisage the compositions contemplated for use in the claimed methods and that the claims lack adequate written description for the claimed composition other that those described in claim 16 and at page 12 of the instant specification.

Applicants respectfully disagree. Applicants assert that amendments to claims 1 and 13-15 provide a positive definition of the subject matter claimed. Amended claim 1, from which claim 13-15, states that the food composition is a daily food ration that contains less than 1600 picomoles of polyamines. As discussed above, a person of ordinary skill in the art would understand the metes and bounds of what a daily food ration would include and that the genus claimed is a daily food ration that contains less than 1600 picomoles of polyamines and that it is effective to act on the NR2-B subunit of the NMDA receptor. The food composition claimed in claim 16 is one specific embodiment of nutritional contents of the daily food ration. As stated on

page 7, line 17 and also on page 12, lines 21-23, the composition recited in claim 16 is one variant of the present invention. Applicants assert that it is implicit in this disclosure that other daily food rations are within the scope of this invention as long as the polyamine content is less than 1600 picomoles.

Based on the claim amendments and the discussion above, Applicants respectfully request the removal of the rejection based on 35 U.S.C. 112, first paragraph.

Rejections over 35 U.S.C. 102(b)

The Office Action rejected claims 1, 13-16, 23-27 29 and 31-32 under 35 U.S.C. 102(b) as being anticipated by Molinoux et al. (CA 21645481). The Office Action asserted that Moulinoux et al teach a composition that can be ingested by man which contains less than about 1600 picomoles/g of polyamine and the specific components of the composition are disclosed in Moulinoux et al. With respect to claims 31-32, the Office Action alleged that the composition in Moulinoux et al may be administered in a dry form to be dissolved extemporaneously in a neutral vehicle suitable for oral or enteral administration. With respect to claims 27 and 29, the Office Action alleged that Moulinoux et al teach administering compositions with the claimed amounts of glucides, lipids, etc. The Office Action also indicated that the polyamine deficient compositions administered are known to induce a powerful antalgic effect in Moulinoux et al. and that the compositions and experiments showing the antalgic effect of these compositions are identical to those of the instant specification. The Office Action concluded that because Moulinoux et al teaches administering compositions identical to those instantly claimed to humans for the same purpose, the claims are anticipated.

Applicants assert that the instantly claimed invention is a new use of a polyamine deficient daily food ration composition. . The disclosure of Moulinoux et al does not disclose the use of the polyamine deficient food ration as claimed in the present invention. The composition in Moulinoux et al. is used as an analgesic (or antalgic) as stated by the Examiner and is related to the reduction of the activity of nociceptive pathways. In contrast, the present invention claims the use of the polyamine deficient diet composition as an anti-hyperalgesic and is related to the inhibition of the overactivation of specific "facilitatory systems". Applicants have attached a Declaration under 37 C.F.R. 1.132 in which the differences between analgesic effect (nociceptive) and anti-hyperalgesic effect (facilitatory systems) are discussed. The Declaration also includes additional experimental data that distinguishes between these two effects. The

Declaration includes a detailed discussion of the two pathways but the main concepts are discussed herein in the context of the 102(b) rejection.

Applicants assert that the claim for an effect on the NR2-B subunit of the NMDA receptor, i.e. the "anti-hyperalgesic effect" for polyamine deficient compositions is different from the previous claim "analgesic effect" as indicated in Moulinoux et al. According to current understanding of pain relief, it is necessary to distinguish between analgesic effect which is defined by an acute decrease of pain sensation related to a tissue injury (see Fig.1, effect 1 in attached Declaration) and anti-hyperalgesic effect which is the specific reduction of pain sensitization process (pain facilitatory systems) which induce exaggerated pain sensation (hyperalgesia) in response to a given nociceptive stimulus (see Fig.1, effect 2) or abnormal pain sensation in response to a non nociceptive stimulus (allodynia).

In fact, these two therapeutic effects are related to two different neurophysiologic processes: the first one (analgesia) is related to the reduction of the activity of nociceptive pathways, and the second one (anti-hyperalgesia) is related to the inhibition of the overactivation of specific "facilitatory systems", which are different from nociceptive pathways, and lead to pain hypersensitivity (exaggerated pain sensation). It is noteworthy that it is now well admitted that these last systems, *i.e.*, pain facilitatory systems, play a critical role in the development of chronic pain.

Applicants assert that these differences between analagesia and anti-hyperalgesia were not known in the 90's when Moulinoux et al. was filed. Therefore, specific experimental models (as clinical approaches) to differentiate hyperalgesia from analgesia were not developed in 1993, leading to the impossibility to distinguish and to claim anti-hyperalgesia from analgesia and therefore to claim for an anti-hyperalgesic effect of PDD (Polyamine Deficient Diet, according to the Moulinoux et al. invention) in 90's.

Furthermore, Moulinoux et al. could not suggest the anti-hyperalgesic effect of the treatment because the test did not study the evolution of pain on the time span but just the instantaneous response to a stimulus. In fact, in Moulinoux et al., the conditions of the experiment could not enable the existence of the anti-hyperalgesic effect and therefore the anti-hyperalgesic effect could not be determined.

Applicants assert that in Moulinoux et al. the food compositions described were used to demonstrate analgesic effects. Anti-hyperalgesic mechanisms were not even understood to be

separate from analgesic effects. Furthermore, the anti-hyperalgesic effects were neither contemplated nor tested in Moulinoux et al. Applicants were the first to discover the use of the polyamine deficient food rations as a method for affecting the NR2-B subunit of the NMDA receptor. The instant Specification is the first to disclose a method for treating a variety of syndromes or pathologies involving the NR2-B subunit of the NMDA receptor. The disclosure of Moulinoux et al does not disclose the use of the polyamine deficient food composition as claimed in the present invention.

In light of the above discussion and claim amendments, Applicants respectfully request the removal of the rejections based on 35 U.S.C. 102(b).

It is believed that the claims, as amended, are patentable over the prior art, and a Notice of Allowance is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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